

PATENT COOPERATION TREATY

PCT

REC'D 11 MAY 2006



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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K1270 PCT	FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/EP2005/002017	International filing date (day/month/year) 25.02.2005	Priority date (day/month/year) 27.02.2004
International Patent Classification (IPC) or national classification and IPC INV. B05B11/00		
Applicant 3M ESPE AG et al		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 27.01.2006	Date of completion of this report 10.05.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Thanbichler, P Telephone No. +49 89 2399-8957 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/002017

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-16 as originally filed

Claims, Numbers

1-19 as originally filed

Drawings, Sheets

1/12-12/12 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☒ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	8-15
	No: Claims	1-7,16-19
Inventive step (IS)	Yes: Claims	11-15
	No: Claims	1-7,16-19
Industrial applicability (IA)	Yes: Claims	1-19
	No: Claims	-

2. Citations and explanations (Rule 70.7):

see separate sheet

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV.

This Authority considers that there are 4 inventions covered by the claims indicated as follows:

- I: Claims 1-7; 14-17 directed to a delivery system for controlled dispensing of a substance
- II: Claims 8-9, 10-11, 18 directed to a sealing system or a method of sealing for a cartridge
- III: Claims 12-13 directed to a self-opening closure system for a cartridge
- IV: Claims 14-15 directed to a delivery system with groove-shaped compartments and the pistons are correspondingly shaped to the compartments

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The special technical features of the first and second group of invention which they have in common are the cartridge with two compartments, with mixing means and a plunger with at least two pistons.

However, these features are already known from D3 (rf. to item V.)

The special technical feature of the second group of invention is a sealing material which will be penetrated by pin rods.

In the third group of invention the special technical feature is a sealing arrangement on inlet and outlet openings.

The special technical feature of the forth group is the special configuration of the compartments with respective pistons.

In conclusion, the groups of claims are not linked by common or corresponding special technical features and define 4 different inventions not linked by a single general inventive concept. The Applicant considers in his communication dated

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

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January 27, 2006 that the application is in line with the requirements of unity of invention, because each of the independent claims recites a cartridge having at least two compartments. However, this feature is known from D3.

The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

As the Applicant has paid the additional fees for all parts of the invention, this Report is based on claims 1-19.

Re Item V.

1 Reference is made to the following document:

- D1: WO 94/22507 A (ELI LILLY AND COMPANY) 13 October 1994 (1994-10-13)
- D2: DE 102 33 925 A1 (MICHELER, CLEMENS; RUHLAND, BERND) 12 February 2004 (2004-02-12)
- D3: DE 201 07 507 U1 (DENTACO DENTALINDUSTRIE UND -MARKETING GMBH) 7 March 2002 (2002-03-07)
- D4: US-B1-6 328 229 (DURONIO JAMES ET AL) 11 December 2001 (2001-12-11)
- D5: EP-A-0 689 874 (BEHRINGWERKE AKTIENGESELLSCHAFT; AVENTIS BEHRING GESELLSCHAFT MIT BESC) 3 January 1996 (1996-01-03)
- D6: US-A-4 978 336 (CAPOZZI ET AL) 18 December 1990 (1990-12-18)
- D7: WO 91/03224 A (POLAK, ROBERT, B) 21 March 1991 (1991-03-21)
- D8: EP-A-1 188 455 (TRANSCOJECT GESELLSCHAFT FUER MEDIZINISCHE GERAETE MBH & CO. KG) 20 March 2002 (2002-03-20)
- D9: WO 97/14460 A (SYNTHELABO, S.A; WARD, WILLIAM, JOHN) 24 April 1997 (1997-04-24)
- D10: US-A-4 738 660 (LUCAS ET AL) 19 April 1988 (1988-04-19)
- D11: US-A-3 098 483 (NIELSEN HELMUTH) 23 July 1963 (1963-07-23)
- D12: US-A-4 813 433 (DOWNEY ET AL) 21 March 1989 (1989-03-21)
- D13: DE 25 14 201 A1 (IDE, WERNER) 14 October 1976 (1976-10-14)
- D14: US-B1-6 290 682 (MYERS JAN WILLEM MARINUS) 18 September 2001 (2001-09-18)

2 INDEPENDENT CLAIMS

2.1 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D3 discloses (the references in parentheses applying to this document):

A delivery system comprising a cartridge (310) having at least two compartments (312; 314) for storing material components and a mixing means for mixing the material components to form a substance (page 13 paragraph 2); a plunger (320; *being an integral part, best seen in fig. 5*) for causing the material components to flow into the mixing means (fig. 16), the plunger having at least two pistons (322; 324) for sliding correspondingly into the at least two compartments (312;314); actuation means (326) for a controlled dispensing of the mixed material components (fig. 9).

2.2 INDEPENDENT CLAIM 8

Document D7 is considered the closest prior art and discloses (the references in parentheses applying to this document):

A sealing system for sealing a cartridge of a delivery system, comprising a sealing material (page 9 last paragraph); a cartridge for storing a material; a plunger with a pin rod corresponding to the compartment where the material is stored (fig. 1); wherein, as the plunger is moved forward, the pin rod is adapted to penetrate the sealing material thereby pushing the material within the compartment forward towards the front of the cartridge such that tight sealing is provided where the sealing material is penetrated by the pin rod (page 10 lines 20-25; page 11 first paragraph).

Claim 8 differs from this known system in that:

The subject-matter of claim 8 consists of at least two material compartments with two pin rods.

The subject-matter of claim 8 is therefore new in the sense of Article 33(2) PCT.

However, the present application does not meet the criteria of Article 33(1) PCT,

because the subject-matter of claim 8 does not involve an inventive step in the sense of Article 33(3) PCT. The reason is the following:

To apply a substance of at least two material components the use of multiple material compartments are well known for a man skilled in the art (cf. to D3). The material components will be mixed by forcing them out of the compartments. Hence, without applying any inventive skill the man skilled in the art would arrive to a solution according to the subject-matter of claim 8.

2.3 INDEPENDENT CLAIM 10

Claim 10 is a corresponding method claim to the subject-matter of claim 8. Therefore the same argumentation as set out under item 2.2 applies to claim 10.

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 10 does not involve an inventive step in the sense of Article 33(3) PCT.

2.4 INDEPENDENT CLAIM 11

The subject-matter of claim 11 seems to fulfill the requirements of the PCT with respect to Article 33(1) and 33(2), because the feature of the two pin rods contacting corresponding pistons underneath the sealing material is neither known nor rendered obvious by the available prior art:

2.5 INDEPENDENT CLAIM 12

Document D14 is considered to be the closest prior art to the subject-matter of claim 12 and discloses an infusion set with a valve arrangement comprising a diaphragm. The infusion set does not provide any pistons for sliding in corresponding material compartments. Hence, the subject-matter of claim 12 seems to fulfill the requirements of Article 33 PCT with respect to novelty and inventive step.

2.6 INDEPENDENT CLAIM 14

The special arrangement of groove shaped compartments with corresponding pistons compressing an exterior surface of the sealing material thereby compressing the compartments so as to press the material components out of the cartridge is neither known nor rendered obvious by the documents cited in the Search Report.

Therefore, the subject-matter is new and inventive according to Article 33 PCT.

3 DEPENDENT CLAIM 16,17

Dependent claims 16 and 17 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

Re Item VII.

Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D3, D7 and D14 are not mentioned in the description, nor are these documents identified therein.

Re Item VIII.

The vague and imprecise statement in the description on page 16 last paragraph implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.

**INTERNATIONAL PRELIMINARY
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(SEPARATE SHEET)**

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According to the Guidelines C-III, 4.10 claim 19 is not allowable.

PATENT COOPERATION TREATY

REC'D 31 OCT 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2005/002017

International filing date (day/month/year)
25.02.2005

Priority date (day/month/year)
27.02.2004

International Patent Classification (IPC) or both national classification and IPC
B05B11/00

Applicant
3M ESPE AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/002017

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item IV.

This Authority considers that there are 4 inventions covered by the claims indicated as follows:

- I: Claims 1-7; 14-17 directed to a delivery system for controlled dispensing of a substance
- II: Claims 8-9,10-11,18 directed to a sealing system or a method of sealing for a cartridge
- III: Claims 12-13 directed to a self-opening closure system for a cartridge
- IV: Claims 14-15 directed to a delivery system with groove-shaped compartments and the pistons are correspondingly shaped to the compartments

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The special technical features of the first and second group of invention which they have in common are the cartridge with two compartments, with mixing means and a plunger with at least two pistons.

However, these features are already known from D1 (rf. to item V.)

The special technical feature of the second group of invention is a sealing material which will be penetrated by pin rods.

In the third group of invention the special technical feature is a sealing arrangement on inlet and outlet openings.

The special technical feature of the forth group is the special configuration of the compartments with respective pistons.

In conclusion, the groups of claims are not linked by common or corresponding special technical features and define 4 different inventions not linked by a single general inventive concept.

Document D1 discloses (the references in parentheses applying to this document):

A delivery system comprising a cartridge having at least two compartments for storing material components (claim 1) and a mixing means for mixing the material components to form a substance; a plunger for causing the material components to flow into the mixing means (page 9 paragraph 2), the plunger having at least two pistons for sliding correspondingly into the at least two compartments (figs. 33,34,42,43,55); actuation means for a controlled dispensing of the mixed material components (page 2 lines 32-35).

2.2 INDEPENDENT CLAIM 8

Document D7 is considered the closest prior art and discloses (the references in parentheses applying to this document):

A sealing system for sealing a cartridge of a delivery system, comprising a sealing material (page 9 last paragraph); a cartridge for storing a material; a plunger with a pin rod corresponding to the compartment where the material is stored (fig. 1); wherein, as the plunger is moved forward, the pin rod is adapted to penetrate the sealing material thereby pushing the material within the compartment forward toward the front of the cartridge such that tight sealing is provided where the sealing material is penetrated by the pin rod (page 10 lines 20-25; page 11 first paragraph).

Claim 8 differs from this known system in that:

The subject-matter of claim 8 consists of at least two material compartments with two pin rods.

The subject-matter of claim 8 is therefore new in the sense of Article 33(2) PCT.

However, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 8 does not involve an inventive step in the sense of Article 33(3) PCT. The reason is the following:

To apply a substance of at least two material components the use of multiple material

known nor rendered obvious by the documents cited in the Search Report.
Therefore, the subject-matter is new and inventive according to Article 33 PCT.

3 DEPENDENT CLAIM 16,17

Dependent claims 16 and 17 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

Re Item VII.

Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

According to the Guidelines C-III, 4.10 claim 19 is not allowable.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D3, D7 and D14 are not mentioned in the description, nor are these documents identified therein.

The vague and imprecise statement in the description on page 16 last paragraph implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.